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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/601,472	06/24/2003	Joseph F. Lessar	P-8615.00	7617

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EXAMINER	
MAYO III, WILLIAM H	

ART UNIT	PAPER NUMBER
2831	

DATE MAILED: 04/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/601,472	LESSAR ET AL.	
	Examiner	Art Unit	
	William H. Mayo III	2831	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-19 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-19 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 04/08/06.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statement filed April 8, 2004 has been submitted for consideration by the Office. It has been placed in the application file and the information referred to therein has been considered.

Specification

2. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

3. The abstract of the disclosure is objected to because in line 1, the abstract contains the term “comprising”, which is improper claim language. The applicant should replace the term with –having--, to provide the abstract with proper language. Correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-2, 4-5, 7, 14-16, and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Publication Entitled ASTM Standard Specification for Wrought 35Cobalt-35Nickel-Chromium-10Molybdenum Alloy for Surgical Implant Applications (UNS R 30035), herein referred to as ASTM). With respect to claim 1, ASTM discloses on Page 1 of 7, a medical electrical lead (i.e. pace maker leads) including an elongated conductor, wherein the conductor includes one wire made of a modified MP35N alloy (i.e. 35N LT alloy), wherein the alloy (35N LT alloy) is formed from a melt composition modified to reduce the amount of titanium inclusion forming elements (see Experimental Procedure, under processing and Table 2 showing the reduction of Titanium). With respect to claim 2, ASTM discloses that the inclusion forming elements include titanium and the modification of the melt composition includes eliminating the titanium as an additive to the melt composition (see Table 2 showing the reduction of Titanium). With respect to claim 4, ASTM discloses that the inclusion forming elements include a gaseous oxygen and nitrogen and the modification of the melt composition includes eliminating the gaseous oxygen and nitrogen under high vacuum conditions (Page 3 of 7, under Figure 2). With respect to claim 5, ASTM discloses that the conductor may be a coiled conductor (see conclusion of page 7 of 7). With respect to claim 7, ASTM

discloses that the minimum diameter of the one wire is between 0.0005-0.01 inches (i.e. 0.007 inches, see Experimental Procedure, under processing). With respect to claim 14, ASTM discloses a medical electrical lead (i.e. pace maker leads) including an elongated conductor, wherein the conductor includes one wire made of a modified MP35N alloy (i.e. 35N LT alloy), wherein the alloy (35N LT alloy) is formed from a melt composition modified to reduce the amount of titanium inclusion forming elements (see Experimental Procedure, under processing and Table 2 showing the reduction of Titanium), which inherently discloses that the titanium based inclusions has an average number of less than 100,000 per square inch (since the titanium content is less than 0.01 (see table 2), the based inclusion would have to be less than 100,000 per square inch, Fig 5 clearly illustrates being less than 100,000). With respect to claim 15, ASTM discloses a medical electrical lead including an elongated conductor, wherein the conductor includes one wire made of a modified MP35N alloy (i.e. 35N LT alloy), wherein the alloy (35N LT alloy) is formed from a melt composition modified to reduce the amount of titanium inclusion forming elements (see Experimental Procedure, under processing and Table 2 showing the reduction of Titanium), which inherently discloses that the average number of titanium based inclusions has a maximum diameter not exceeding approximately 1μ (Fig 3 clearly illustrates inclusion being measured by 1 μm). With respect to claim 16, ASTM discloses that the conductor may be a coiled conductor (see conclusion of page 7 of 7). With respect to claim 18, ASTM discloses that the minimum diameter of the one wire is between 0.0005-0.01 inches (i.e. 0.007 inches, see Experimental Procedure, under processing).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 3, 9-10, and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Publication Entitled ASTM Standard Specification for Wrought

35Cobalt-35Nickel-Chromium-10Molybdenum Alloy for Surgical Implant Applications (UNS R 30035), herein referred to as ASTM). ASTM discloses on Page 1 of 7, a medical electrical lead (i.e. pace maker leads) as disclosed above with respect to claim 1 above

However, ASTM doesn't necessarily disclose the alloy containing less than approximately 0.001 % titanium (claim 3).

With respect to claim 3, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the alloy of ASTM to comprise the alloy containing less than approximately 0.001 % titanium, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller, 105 USPQ 233.*

With respect to claim 9, ASTM discloses on Page 1 of 7, a medical electrical lead (i.e. pace maker leads) including an elongated conductor, wherein the conductor includes one wire made of a modified MP35N alloy (i.e. 35N LT alloy), wherein the alloy (35N LT alloy) is formed from a melt composition modified to reduce the amount of titanium inclusion forming elements (see Experimental Procedure, under processing and Table 2 showing the reduction of Titanium). With respect to claim 10, ASTM discloses that the conductor may be a coiled conductor (see conclusion of page 7 of 7). With respect to claim 12, ASTM discloses that the minimum diameter of the one wire is between 0.0005-0.01 inches (i.e. 0.007 inches, see Experimental Procedure, under processing). With respect to claim 7, ASTM discloses that the minimum diameter of the

one wire is between 0.0005-0.01 inches (i.e. 0.007 inches, see Experimental Procedure, under processing). With respect to claim 14, ASTM discloses a medical electrical lead (i.e. pace maker leads) including an elongated conductor, wherein the conductor includes one wire made of a modified MP35N alloy (i.e. 35N LT alloy), wherein the alloy (35N LT alloy) is formed from a melt composition modified to reduce the amount of titanium inclusion forming elements (see Experimental Procedure, under processing and Table 2 showing the reduction of Titanium), which inherently discloses that the titanium based inclusions has an average number of less than 100,000 per square inch (since the titanium content is less than 0.01 (see table 2), the based inclusion would have to be less than 100,000 per square inch, Fig 5 clearly illustrates being less than 100,000). With respect to claim 15, ASTM discloses a medical electrical lead including an elongated conductor, wherein the conductor includes one wire made of a modified MP35N alloy (i.e. 35N LT alloy), wherein the alloy (35N LT alloy) is formed from a melt composition modified to reduce the amount of titanium inclusion forming elements (see Experimental Procedure, under processing and Table 2 showing the reduction of Titanium), which inherently discloses that the average number of titanium based inclusions has a maximum diameter not exceeding approximately 1μ (Fig 3 clearly illustrates inclusion being measured by 1 μm). With respect to claim 16, ASTM discloses that the conductor may be a coiled conductor (see conclusion of page 7 of 7). With respect to claim 18, ASTM discloses that the minimum diameter of the one wire is between 0.0005-0.01 inches (i.e. 0.007 inches, see Experimental Procedure, under processing).

However, ASTM doesn't necessarily disclose the alloy containing less than approximately 0.001 % titanium (claim 9).

With respect to claim 9, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the alloy of ASTM to comprise the alloy containing less than approximately 0.001 % titanium, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller, 105 USPQ 233.*

10. Claims 6, 8, 11, 13, 17, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Publication Entitled ASTM Standard Specification for Wrought 35Cobalt-35Nickel-Chromium-10Molybdenum Alloy for Surgical Implant Applications (UNS R 30035), herein referred to as ASTM) in view of Applicant's Own Admission of Prior Art (herein referred to as AOAPA). ASTM discloses on Page 1 of 7, a medical electrical lead (i.e. pace maker leads) as disclosed above with respect to claims 1, 9, & 14 above.

However, ASTM doesn't necessarily disclose the conductor being a cable conductor (claims 6, 11, & 17), nor the minimum diameter of the one of more wires being between 0.005-0.003 inches (claims 8,13, & 19).

With respect to claims 6, 11, & 17, AOAPA teaches conductors comprising numerous fine stranded wires are well known in the art for being utilized as pacemaker conductors (see Background of the Invention). With respect to claims 8, 13, & 19, AOAPA teaches that the formation of small diameter leads, such as 0.001 inches or

less are well known for being utilized as multiple leads or medical electrodes (see Background of the Invention, Page 2).

With respect to claims 6, 11, & 17, it would have been obvious to one having ordinary skill in the art of cables at the time the invention was made to modify the pacemaker conductor of ASTM to comprise the pacemaker cable conductor configuration as taught by AOAPA because AOAPA teaches that such a configuration is well known in the art for being utilized as pacemaker conductors (see Background of the Invention).

With respect to claims 8, 13, & 19, it would have been obvious to one having ordinary skill in the art of cables at the time the invention was made to modify the conductor of AST to comprise the conductor minimum diameter of the one of more wires being between 0.005-0.003 inches as taught by AOAPA because AOAPA teaches that such a configuration is well known for being utilized as multiple leads or medical electrodes (see Background of the Invention, Page 2) and since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller, 105 USPQ 233.*

Conclusion

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. They are Mar (Pat Num 5,483,022), Verness (Pat Num 6,061,598), Avellanet (Pat Num 6,248,955), Barsne (Pat Num 6,720,497), Dickenson

(Pat Num 7,015,392), Sass (Pat Num 2002/0068965 A1), Doan et al (Pat Num 2002/0147488 A1), Ebert et al (Pat Num 2005/0004643 A1), Shoberg et al (Pat Num 2005-0027342 A1), Kallok et al (Pat Num 4,355,646), Kane et al (Pat Num 4,591,393), and Breyen et al (Pat Num 5,433,744), all of which discloses medical leads being made of MP35N.

Communication

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Mayo III whose telephone number is (571)-272-1978. The examiner can normally be reached on M-F 8:30am-6:00 pm (alternate Fridays off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dean Reichard can be reached on (571) 272-2800 ext 31. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

William H. Mayo III
Primary Examiner
Art Unit 2831

WHM III
March 27, 2006